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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,962	09/08/2003	Mendy S. Maccabee	49321-102	3139

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
12/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,962	MACCABEE ET AL.	
	Examiner	Art Unit	
	JENNIFER M. KIM	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 24, 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 6-8, 21 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-8,21 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/25/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 24, 2009 has been entered.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6-8, 21 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shigeyama (Vitamin A metabolism in nasal and paranasal disease, 1968) in view of Biesalski (U.S.Patent No. 5,556,611) of record, Belloni (U.S.Patent No. 6,339,107 B1) of record and Popp et al. (1995).

Shigeyama teaches that inadequate nutrition especially deficiencies in nutrients such as vitamins A and D is the cause of chronic paranasal sinusitis. Shigeyama teaches that vitamin A has a prophylactic effect, and giving vitamins A and D to infants suffering from **paranasal sinusitis** had a curing effect in light cases. (page first full paragraph 34-35). Shigeyama teaches that vitamin A plays an important role in maintaining the function of mucosal epithelia. Shigeyama teaches that the patients having **chronic paranasal sinusitis** were injected with water-soluble **vitamin A** palmitate (Chokola A) by intramuscular injection. Shigeyama teaches that vitamin A is mainly distributed in the epithelial layer, gland tissue and vessels. Shigeyama teaches that their findings revealed that serum vitamin A decreased in chronic paranasal sinusitis patients, suggesting that reduced vitamin A levels caused local regressive changes in mucosa that facilitated infection, and exerted a steady influence on the autonomic nervous system that facilitated allergic changes. These findings also suggest that poor circulation formed between decreased vitamin A and local lesions and also liver function, which simultaneously acted causally to partially inhibit curing and

foster development of a chronic condition. (pages 37 first paragraph, 40, 41, 58, 79 first full paragraph,101).

Shigeyama does not expressly teach topical delivery to sinus cavity, the formulations set forth in claim 6, the effective amounts set forth in claim 9 and the subject had undergone a surgery set forth in claim 27.

Biesalski teaches a pharmaceutical preparation consisting of **retinoic acid** as an active substance suitable for **a topical** treatment of **mucosal disease** in man and animal. (abstract). Biesalski teaches the preparation can be formulated in an **aerosol** formulation. (abstract). Biesalski teaches the effective amount of the active substance is from **0.01-50% by weight**. (column 6, line 44). This range encompasses and touches Applicants' amounts set forth in claim 8. Biesalski teaches that the preparation is effective for treating **functional impairments in the mucous membranes** of humans and animals, in particular in the respiratory epithelium and the epithelia of the **nose-throat cavity**. Biesalski teaches that the treatment is also useful in **reduced activity of the ciliated epithelium** and disturbances of the mucous membranes of the respiratory tract. (column 10, lines 24-45). Biesalski teaches the preparation is effective for treating acute and chronic bronchitis, acute and chronic functional disturbances due to impairment of tracheobronchial epithelium and bronchopulmonary dysplasia.

Belloni teaches that topical administration of retinoic acid can be formulated as solutions, gels, ointments, creams, suspension, etc. as are well-known in the art. (column 8, lines 14-17). Belloni teaches that retinoic acid can be formulated for oral liquid preparations such as suspensions, elixirs and solutions, as well as **transmucosal**

and **buccal** administration. (column 8, lines 35-40, line 40-65, column 9, lines 1-6). Belloni teaches that retinoic acid can be formulated as a **depot preparation**. (column 10, lines 35-45).

Popp et al. teach that it has been known for decades that vitamin A and its derivatives can enhance various aspects of wound repair. (page 46, left-hand side, first paragraph).

It would have been obvious to one of ordinary skill in the art to employ Vitamin A for the treatment of sinus disease such as paranasal sinusitis or promoting sinus wound healing in a subject because Shigeyama teaches that vitamin A is useful as a prophylactic agent for curing paranasal sinusitis and because vitamin A is known for decades for its enhancement on various aspect of wound repair as taught by Popp et al. One would have been motivated to make such a modification in order to achieve an effective therapeutic benefit of vitamin A in treatment of paranasal sinusitis caused by lack of vitamin A as taught by Shigeyama.

It would have been obvious to one of ordinary skill in the art to administer effective amount of vitamin A via topical delivery to sinus cavity of the subject having sinus disease or sinus wound because the effective amounts and the topical formulation of vitamin A for the treatment of disorders related to functional impairments in the mucous membrane and epithelium and the epithelia of nose-throat cavity and paranasal sinusitis is well taught by Shigeyama as modified by Biesalski and Belloni. It would have been obvious to one of ordinary skill in the art that the topical delivery of vitamin A formulation taught by Biesalski and Belloni would absorb or penetrate to paranasal

cavity in the treatment of paranasal sinusitis in Shigeyama's patients because the amounts and the formulations of vitamin A taught by Biesalski and Belloni are the same topical formulations as instantly claimed. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. The prior art teaches the identical chemical structure, therefore, the properties applicant discloses and/or claims (topically delivering to sinus cavity) are necessarily present.

It would have been obvious to one of ordinary skill in the art to employ retinoic acid preparation taught by Shigeyama as modified by Biesalski and Belloni and Popp et al for the treatment of any sinus wound healing associated with ciliated epithelium healing or ciliated mucosa including any cause of such damage including the specific sinus surgery set forth in claim 27 because both Shigeyama and Biesalski et al teach that the retinoic acid preparation is effective for the treatment of impaired ciliated epithelium and disturbances of the mucous membranes in general including **paranasal sinusitis** and that Popp et al. teaches the wound healing effect of tretinoin (retinoic acid) was known at the time the invention was made. One would have been motivated to employ the retinoic acid preparation in the methods taught by Shigeyama as modified by Biesalski, Belloni and Popp et al. for a condition of damaged ciliated epithelium or a condition of disturbances of the mucous membranes at any cause including the surgical intervention in order to effectively treat the condition and obtain the known wound healing effect of retinoic acid. There is a reasonable expectation of successfully treating damaged ciliated epithelium in **paranasal sinusitis** because cited references

Shigeyama, Biesalski, and Belloni teach the effectiveness of vitamin A for treating damaged ciliated epithelium or damaged respiratory walls in man or animal including paranasal sinusitis and its well known would healing effect.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Response to Arguments

Applicant's arguments with respect to claims 1, 6-8, 21 and 24-28 have been considered but are moot in view of the new ground(s) of rejection.

None of the claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is

(571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
December 22, 2009